UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK
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IN RE: HEARTWARE INTERNATIONAL, INC. SECURITIES LITIGATION,

16 CV 0520 (RA)

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New York, N.Y.
March 16, 2018
11:06 a.m.

Before:

HON. RONNIE ABRAMS,

District Judge

APPEARANCES

BERNSTEIN LITOWITZ BERGER & GROSSMANN, LLP
Attorneys for Plaintiffs
BY: JOHN RIZIO-HAMILTON, ESQ.
ABE ALEXANDER, ESQ.

WILMER CUTLER PICKERING HALE & DORR LLP
Attorneys for Defendants
BY: JEREMY T. ADLER, ESQ.
MICHAEL G. BONGIORNO, ESQ.

(In open court)

(Case called)

MR. RIZIO-HAMILTON: Good morning, your Honor. John Rizio-Hamilton from Bernstein Litowitz Berger & Grossmann for the lead plaintiff.

MR. ALEXANDER: Good morning, your Honor. Abe Alexander, Bernstein Litowitz, for the plaintiff.

THE COURT: All right. Good morning.

MR. ADLER: Good morning, your Honor, Jeremy Adler from Wilmer Hale.

MR. BONGIORNO: Mike Bongiorno from Wilmer Hale for the defendant trusts.

THE COURT: All right. Good morning. We're here to discuss defendant's motion to dismiss. I'm happy to hear you out.

MR. BONGIORNO: Sure, your Honor.

THE COURT: I'm just going to ask you to bring the microphone close to where you're standing. Thank you.

MR. BONGIORNO: That's about as close as I can get it, I think.

THE COURT: Go ahead.

MR. BONGIORNO: So, your Honor, for the defendants, we represent HeartWare and Mr. Godshall, who was the CEO of HeartWare, which was a small medical device company in Framingham, Massachusetts, with the facility -- manufacturing

facility down in Florida, since acquired by a larger company, but at the time, that's what it was.

THE COURT: I've, of course, read all the briefs, which, by the way, I thought were excellent. But I'm happy to hear you out.

MR. BONGIORNO: Okay, your Honor. I'll skip all the background then and jump right into what I think are a few important points. I think the heart of the issue here, there are two things, one is falsity and the other is scienter. On both points, I think where the complaint falls down is its reliance on ex-employees who don't say anything close to what the plaintiffs would like them to have said, the way they characterize them elsewhere in the complaint, other than when they're focusing on the ex-employees themselves, and most certainly in the opposition brief.

Because the theory, apparently, is that HeartWare plowed forward with this trial on MVAD, knowing that it was going to fail. And the theory behind that, of course, is that HeartWare got a warning letter from the FDA, which dealt with certain processes, validation, documentation, all of which related to a different product that was already on the market, the HVAD product.

The HVAD product had been on the market for a while, was a fairly successful product. There was some competition out there. HeartWare was developing a new product, a smaller

version of the same pump, or a similar pump and was trying to get that into clinical testing.

The class period here -- and we've all seen a lot of these cases because whenever there's a bump in the road in the FDA process and the stock price goes down, we see a case like this. So in a lot of these cases, the class period starts with some fairly spectacular announcement about some great results of a clinical trial or something wonderful.

Here, the class period starts kind of with a thud. I think it's June 10th of 2014, where the CEO of HeartWare isn't talking about something wonderful. He's actually talking about the warning letter, and in the warning letter he says, gosh, I got one of these in my other company and it just killed us. It was years, it took forever, et cetera, going to try to do better this time. And then he couches it with all sorts of cautionary language about, you know, the problems that might arise but they're going to throw resources at it.

The plaintiffs don't dispute that the company threw resources at it. They just say we didn't do a good job. We disclosed millions of dollars that we've spent, in various orders. There is $10 millions worth of spending. The plaintiffs dispute. They admit the amount. They just say, we don't know what it was spent on, and we have these ex-employees who say things were messed up, and they weren't doing a good job, and they were ignoring problems and, therefore --

THE COURT: They also say that misstatements were made about what kind of progress was with being made, if any, among other things.

MR. BONGIORNO: They most certainly say that, your Honor, but they don't have the allegations to back that up. They rely on folks who had either no contact with Mr. Godshall, or didn't even work there during the class period, or both.

So the big, lengthy explanation of their basis for a lot of this comes from Former Employee No. 1. Former Employee No. 1 did not work at the company during the class period. So employee -- Former Employee No. 1 says there was this problem, there was this problem, there were meetings, people definitely knew, which I think is code for they must have known but I don't really know but I'm assuming it.

There's only one person who claims to have had one interaction with Godshall, and that's Former Employee No. 1, who didn't work there during the class period.

THE COURT: What about Former Employee No. 5? For example, one of the allegations is that on October 30th, 2014, on a third-quarter earnings call, Godshall stated that we've made significant progress in our efforts to address the FDA warning letter issues and that we've upgraded many of our key procedures and are already seeing a positive impact from the new approach.

According to Former Employee 5, who was allegedly a

validation and verification tester from August 2012 to March 2015 and who worked on MVAD, including its controller, after receiving the warning letter, the manufacturing testing and validation process at HeartWare -- and this is a quote now -- didn't change, rather, "we were just doing exactly what we were doing before receiving the letter."

Why is that not a sufficient allegation of a false statement?

MR. BONGIORNO: Well, a couple of things, your Honor. First of all, again, no contact with Godshall; so on the scienter piece, I don't know how you get to scienter. But I know your Honor's question addressed falsity; so let me address falsity.

The statement that your Honor just quoted, I don't think is a statement on which a securities fraud claim can be based. It's a pretty general statement about optimism about what's going on and what they're doing at the company.

The complaints that he has, he or she has, Former Employee No. 5, have to do with the suction alarm being defective. They were triggered in extreme conditions and the impeller was, however you say that word, was insufficiently tested as of March of '15.

So the first implant of this device isn't until, I think, five months after that. So exactly what was going on at the time this person left versus what was going on months

later, when the device was first implanted, this person certainly can't speak to. What Godshall knew about that, this person certainly can't speak to.

One of the things that this person claims about is that the battery could be charged up to 99 percent; so HeartWare lowered it to 97 percent, the threshold for saying the battery is fully charged. That's one of the specific things that Former Employee No. 5 says. Hard to believe that it is securities fraud for Godshall to say, things are going well and progressing in terms of responding to the warning letter, which again had to do with the HVAD processes, but I understand your Honor's point, which is processes are processes.

THE COURT: If he's saying, we made significant progress and that we've upgraded many of our key procedures -- and I'm, obviously, not weighing it on merits, of course -- but if, in fact, it turns out to be true that they hadn't made any progress and/or upgraded any of the key procedures, why is that not a material misstatement?

MR. BONGIORNO: Well, first of all, I do think it's too general for it to be a statement on which a potential purchaser of the stock can rely. I think that's corporate optimism and that's puffing and that's a non-material statement in the first place. So it can't be a material misstatement if it's not material in the first place.

But Former Employee No. 5 certainly can't speak to that general a statement and say it's not true because of his -- his or her narrow window into certain validation processes in general at the company.

For Godshall to say we've made significant progress could absolutely be true, regardless of what this person says or saw. It is undoubtedly the case --

THE COURT: Is it not plausible that it's true, that he was right?

MR. BONGIORNO: I don't think that's the standard, your Honor, for deciding whether or not -- whether or not a statement is true or not based on a former employee's limited, narrow explanation of what he or she saw.

Is the allegation plausibly true based solely on one employee's observation of a couple of validation tests? No. That's not enough for a fraud claim, and it's certainly, certainly, and I understand your Honor didn't ask this question, but it's certainly not enough for scienter, which is a critical piece of our motion.

If you put together, you know, all six former employees, I still don't think you add up to a plausible claim that something specific that Godshall said was false or misleading when it was made because, again, I think much of what he said is just general types of corporate optimism, we're on track, we're doing well, we're making progress, that type of

stuff.

We've cited dozens -- well, maybe not dozens, but we cited as many cases we thought were appropriate on the point that those types of statements are not statements on which a securities fraud claim can be based.

Putting that aside, whether or not you think that's a statement of the Court -- I apologize, the Court thinks that a statement can be relied upon by an investor, I don't think there is enough here from the former employees to say that anything specific that Godshall said was false when it was made and certainly, certainly there's not enough for scienter, regardless of what anyone thinks about the falsity or lack thereof of the sufficiency of the pleadings on that point.

So I think that's sort of the heart and soul of our motion, and the heart and soul of what the infirmities are with the case because, obviously, we could go one by one through these employees, but I know the Court is familiar with them and is focusing on what the Court would like to understand better.

But for each employee, there are gaps, there are holes, and there's nothing that takes what the employee said and what the employee saw and contrasts it with what was actually happening to the point where you could say that there was a false or misleading statement.

You know, there's stuff about things like the qPulse algorithm and supposed infirmities with that. But if you

compare what they say in the beginning of the complaint in paragraph 16 about somebody observed it, and they spoke to Godshall about it, and you go to the actual employees' statement in the complaint -- which I think are later, in the 80s and 90s paragraphs, in the complaint -- and you look at what the employee actually said and you try to figure out, when did this person work here? What did they do?

Oh, this person was just a software engineer, and they are trying to tell the Court that the red blood cells or the blood cells were being ground by the impeller and that could create thrombosis. What does a computer programmer software programmer doing trying to tell us that? That's not a doctor. That's not a scientist. That's a software engineer. And that statement is really not even attributed to anyone. It's just in the complaint in the section about the employees. I assume the employee must have told the private investigators for our plaintiffs that statement, but they have no basis to say that.

They can't possibly know something like that. That's somebody who is a lot smarter than I am in an area that I don't understand, but it's computer software programming associated with getting the device to do things. It's not diagnosing what about this device, if it goes wrong, could cause thrombosis. The person who's writing code has no idea about that.

What they do have an idea about is what happened, which is, unfortunately, this device was implanted in folks

over in Europe, and it didn't work the way we wanted it to. There's no doubt about that, and there were thrombosis events, and that is not a good thing. And we stopped the trial when we figured that out.

But a software programmer, who's saying, oh, the impeller is grinding the blood cells, whatever? They can't tell us that they knew, in 2014, that that problem with the software was going to cause this issue in these patients. Of course, we didn't put this device into patients if we thought it was going to do that.

And what you don't see in the complaint, which would be a problem, and I'm sure the Court may be wondering, okay, Mr. Bongiorno, what is it these employees could have told us that would have made what Godshall said false? And the answer to that question is pretty simple. He said, we can't get this device to create thrombosis in bench testing, and so we think it's going to have a lower thrombosis rate when all is said and done. We think this is a great device. And you don't see a single person put in this complaint that's a lie. There were thrombotic events in the bench testing. That happened. They didn't want you to know that; so they didn't tell you that, and they told you the exact opposite.

I can see that, if that's in there, that's a different issue. What do are we doing telling people that this didn't happen when it did? Contemporaneous knowledge of falsity,

that's what's missing. It's missing from the falsity element and it's missing from the scienter element. I think that's really the key to our motion, your Honor.

THE COURT: All right. Thank you very much.

Yes, hi.

MR. RIZIO-HAMILTON: Good morning, your Honor.

THE COURT: Good morning.

MR. RIZIO-HAMILTON: I'll try and be brief and just address some of the points that my colleague mentioned.

THE COURT: Why don't you respond to the argument that these are just statements reflecting corporate optimism, they're forward looking, they're opinions.

MR. RIZIO-HAMILTON: Sure. So the statements at issue in this case are factual representations, at their core, about two things principally. One is the current status, progress and success of the company's remediation efforts; and two, is the current safety profile of the device which is, in fact, you know, derived from the supposedly rigorous testing that the company has undertaken.

So, for instance, there are statements such as, we have, quote, made significant progress in our effort to address the FDA warning letter. We have upgraded many of our key procedures and are already seeing a positive impact from the new approach.

That kind of statement is factual, and it is certainly

present tense, and there are many, many others of that ilk in the complaint. For instance, you know, later in the class period, defendant Godshall states that HeartWare has, quote, totally overhauled our R and D procedures. He states that HeartWare is really tight now in terms of open issues that could have resulted in challenges from regulators.

So there's a variety of statements in the complaint, your Honor, and we submit that the overwhelming majority are present tense, they are factual and they are highly material to investors and that, in fact, have been held actionable by courts in the other cases we cite in our brief, like the *Mulligan* case is one example, but there are others in the brief. I won't go through them chapter and verse. I don't think there's any need. The Court is familiar with them.

But I do want to underscore the materiality in these statements because a lot of what my colleague was saying was, sort of, meant to make the point that the statements are not of a nature that an investor would consider significant. Nothing could be further from the true. The fact of the matter is that the status of the company's remediation efforts and its success in those efforts was first and foremost on the mind of investors.

Defendant Godshall himself stated that remediating the warning letter was the company's top priority. Analysts, on conference call, after conference call, repeatedly asked

defendant Godshall about the status of the company's remediation efforts. And in their reports recommending HeartWare stocks, analysts repeatedly relied on Godshall's statements and, in fact, often repeated them in those reports to the market at large.

So I think that all those facts, kind of taken together, demonstrate the materiality of the statements. And in similar circumstances, other courts have agreed.

Also supporting materiality is the fact that, you know, defendant Godshall repeatedly said that their success in remediating the warning letter very much implicated MVAD and that MVAD was the company's No. 2 priority and was, in fact, the key to reigniting HeartWare's stalled road. The remediation efforts themselves and their implications for the company's ability to implant MVAD in humans and ultimately bring it to market, further underscores the materiality of those particular remediation statements.

As far as the safety profile statements, and particularly the statements relating to the propensity of the device to cause pump thrombosis, those were of utmost importance to the market. There was, in fact, early studies of VAD devices that showed about a two to four percent thrombosis rate, fueled market optimism and market growth.

As we allege in the complaint, at the start of the class period, there was a New England Journal of Medicine

article that was published showing an 8 percent thrombosis rate for, I believe, HeartMate II, which was HVAD's principal competing device, and that actually caused market contractions. And analysts specifically reported that that was a major challenge for the industry to overcome if it wanted to be growing again.

And so analysts and investors were intensely focused on safety profile statements, particularly if those statements concerned the device's propensity to thrombus. And those are precisely the kind of safety statements at issues here.

THE COURT: Do you want to respond to Mr. Bongiorno's argument regarding scienter?

MR. RIZIO-HAMILTON: Yes, your Honor.

So we think that there are ample facts in the complaint that give rise to an inference of scienter that are at least as strong as the opposing inference. First of all, with respect to defendant's statements that the adverse events that they had observed in the CE Mark trial, which they did not disclose at all until market rumors swirled and required them to speak, they said they were typical of those observed in other studies.

But at the time the defendants made that statement, there's no dispute that they were in possession of data showing that the patients in the CE Mark trial were thrombosing at a rate that was vastly in excess of prior rates that had fueled

market optimism and even vastly in excess of the 8 percent rate for HeartMate II that had fueled market concern.

So the fact that defendants were in possession of that data at the time that they assured the market, and those statements were reassuring statements, intended as such, the fact that defendants were in possession of that data at the time when they reassured the market as they did is compelling evidence of scienter. That's point one.

Point two, throughout, defendant Godshall was repeatedly kept apprised of the facts concerning, A, the lack of remediation efforts at HeartWare; and, B, the fact that the testing that they did perform showed serious safety defects, including the defects that ultimately materialized in the CE Mark trial.

Former Employee 1 reported that defendant Godshall usually attended the monthly program board oversight -- project board oversight meetings, where the defects with the qPulse, with the suction alarm and the controller were discussed. There were weekly MVAD team meetings that defendant Godshall's direct reports attended, Mr. LaRose and Mr. Strong, where these same defects were reported.

And following these meetings, minutes were prepared reporting the defects that were distributed to defendant Godshall and many other senior executives at the company. That's point two. Defendant Godshall, there was a steady

stream of information directly to defendant Godshall about these defects at the time he made his statements and the state of the company's remediation efforts. That's point two.

Point three, defendant Godshall, himself, said that he was paying close personal attention to these very issues. Again, remediating the warning letter was the company's top priority, and MVAD was its second-most important priority. And defendant Godshall repeatedly stated that he was paying close personal attention on both scores. And so his statements very much bolster and corroborate the report of Former Employer 1, that he was, in fact, being informed. That's point three.

Point four, defendant Godshall was speaking about issues that were, as I've noted, the most significant ones facing the company. This is, in essence, a core operations argument, and whatever one may think about the viability of the core operations doctrine as an independent basis for proving scienter, that's kind of by the wayside here because we're not simply relying on the core operations doctrine.

The case law is to the effect that core operations allegations, such as those that we have here, do indeed bolster the inference of scienter when there is additional evidence showing that defendants had access to information contradicting their statements, such as the case here as I've noted. The importance of the remediation efforts and the importance of MVAD to HeartWare's business are indeed supplementary evidence

of scienter.

And, finally, your Honor, we believe that the Valtech -- the Valtech transaction is additional scienter evidence. When this transaction was announced, to say the market was perplexed is an understatement. No one understood why, if the company was, in fact, so bullish about MVAD, with approval potentially just months away, it would agree to give up about a third of the value of its equity in exchange for a company in a completely other line of business when, should the approval be granted as defendants said they were confident, the value of that equity would increase dramatically in the near term.

And, in fact, Wells Fargo analysts said that the announcement of that transaction really makes us doubtful. It calls into question whether defendant Godshall is truly bullish on MVAD, as he's repeatedly said. And indeed, the company's largest shareholder, frankly, said that when transformative corporate acquisitions like this are announced, it often leads one to question management's faith in the company's core business.

Such an acquisition, like Valtech, could only be approved and consummated with the knowledge of the company's highest executive, like defendant Godshall. So to the extent that the Valtech transaction was motivated by a desire to hedge MVAD precisely because defendant Godshall was deeply concerned

about the device, that too supports an inference of scienter.

The timing of that transaction bolsters the inference because the transaction was announced on September 1st, 2015. The market said, this makes us think you're really worried about MVAD. And, in fact, one week later, the company pauses, literally one week later, the company pauses the CE Mark trial because the controller is literally falling apart. Just seven weeks after the trial started and one week after Valtech is announced, the company says, we have to pause, the controller is falling apart, physically.

Then, a month after that, about a month-and-a-half after Valtech is announced, the rumors begin swirling about adverse events and defendants, you know, falsely reassured the market in response, with the trial still paused, and then soon thereafter, in January, the company is forced to announce that approximately half the patients have suffered these very severe thrombotic events that the market was intensely concerned about.

So, you know, the timing of that transaction and the subsequent events further bolster the inference that it was undertaken because management was, contrary to its public statements, actually quite concerned about the device.

THE COURT: Finally, why don't you address briefly loss causation and why the stock decline was in reaction to the allegedly false statements as opposed to, you know, the spate

of bad fortune relating to the development of this innovative project.

MR. RIZIO-HAMILTON: Sure. So, you know, as your Honor is well aware, loss causation is subject to only rule 8 notice pleading, and it is typically an issue for expert and fact evidence at trial, and generally shouldn't be decided at the pleading stage.

We think that the complaint here contains many allegations that adequately allege loss causation, at a minimum, under rule 8. So the sort of core of defendant's statements obscured from the market the truth that the company's processes hadn't been sufficiently remediated, and the risk that the device had not been adequately tested and, in fact, had a safety profile that was significantly more dangerous than the market had been led to believe. That's kind of the sort of risk that was obscured and hidden by defendant's statements.

The disclosive events each constituted a materialization of that hidden risk. The first is the September 1st announcement of the Valtech transaction, and defendants say, you know, a corporate transaction can't reveal a risk that the device is deeply flawed and dangerous. The problem is that here -- or the problem in their argument is here we have very specific market reactions saying almost exactly that, because the Wells Fargo analysts said that this

transaction reveals to us that the company isn't as bullish on MVAD as it has led on, which caused very serious market concern about the device, and they said that that was, in fact, the most common question they got from investors.

So we have very detailed facts demonstrating that the announcement of the transaction revealed to the market the risk that the device was not as represented and that management's confidence in it was not as represented. And, indeed, this was confirmed by the fact that in the weeks following the announcement of that transaction, defendant Godshall went on essentially a PR campaign to reassure the market that that was not the case.

He specifically acknowledges that the market took that from the announcement of the transaction, took that from the disclosive event and tells the market that there's nothing to worry about, which was not true. So that's the theory for disclosure one.

The second and third disclosures on October 12th and then later in January 2016, both confirmed the disclosure of, in the case of the October event, potentially adverse events that had been experienced in the trial; and then in January, the confirmation that those adverse events had, in fact, occurred and it affected almost 50 percent of the patients that had been implanted with the device.

In both cases, the disclosure of the adverse events is

a materialization of the risk that the company had not thoroughly tested the device, did not have a handle on its true safety, and that the device was, in fact, materially more dangerous than had been represented. That is within the zone of risk concealed by defendant's misstatements and, therefore, satisfies the standards for pleading loss causation most recently articulated in by the Second Circuit in the Vivendi decision.

THE COURT: All right. Thank you. Do you want to respond briefly?

MR. BONGIORNO: Yes, your Honor. Thank you. Let me focus on the scienter piece because my colleague spent a lot of time on that.

I think he gave you five reasons. They don't add up. The first one, when the Court asked about scienter, he said adverse events in the CE Mark trial, patients vastly in excess of -- thrombosing vastly in excess of other products, similar products. First of all, that's in late 2015 for a class period that starts in June of 2014. Hard to base scienter on our knowledge of adverse events in a trial that started in late 2015 for a class period that starts well over a year before.

The theory, apparently, is that we acted with scienter because we didn't disclose the number of thrombotic events at the time we disclosed that there were adverse events in the trial that were typical of this type of device.

But what's left out of that equation? I don't know how that's a scienter argument because, again, that's over a year into the class period. How that shows that they're acting with scienter over a year earlier, I don't know, but in terms of the falsity of that statement in the first place, which he's saying shows scienter because Godshall knew how many adverse events there were and he didn't say how many adverse events there were. He said he wasn't going to reveal the number of adverse events.

Hard to base a securities fraud claim on a question that somebody says they're not going to answer. How is it fraud when someone says, how many? And you say, I don't think it's responsible for me to say right now. We're at the very beginning of the trial. That is not securities fraud. That's a question that he didn't answer.

Second of all, the market understood what was going on. He used the plural, the analysts' reports that he likes to rely on to say here's what the market understood what's happening, said there was a cluster of thrombotic events. That's a whole lot more than one. There were only three. There were only 11 patients enrolled at that point and, again, that's a class period that shouldn't exist at all, but if it does, starts in October of 2015, not June of 2014.

His second point on scienter, he said, we cite in the complaint that Godshall was repeatedly apprised of the lack of

remediation efforts throughout the class period. That is not what the complaint says. The complaint says no such thing.

What did he mention? He mentioned Former Employee No. 1. Throughout the class period, he wasn't even there -- he or she wasn't even there during the class period. So Former Employee No. 1 doesn't get you anywhere.

Weekly meetings attended by Godshall's direct reports. That's not Godshall being apprised. That's his direct reports maybe being apprised, I don't know, but it's certainly not him.

He says minutes of these meetings reporting the defects were distributed. The complaint doesn't say that. The complaint doesn't say anything about what's in those meeting minutes. It says minutes were kept of the meetings, and they were distributed. Did any of these former employees see those meeting minutes? Do they know what they said? Do they know whether or not it went to Godshall? Do they know if he read them? Did it happen during the class period? We don't know the answer to any of those questions.

Third scienter point, he was paying attention, and he was the CEO and it was important. We don't dispute that he was paying attention. What we dispute is what he learned by paying attention because there's --

THE COURT: This was a relatively small company; am I right?

MR. BONGIORNO: It is certainly smaller than it is

now. I mean, now it's part of Medtronic. At the time, there were hundreds of employees. Now, there are many thousands. But a lot of what's going on in the complaint is happening in Florida, not in Framingham, Massachusetts. It's not a mom-and-pop corporation. It was a publicly traded company with lots of employees, scientists, computer software programmers. They were doing all their own work in-house.

This was not -- it was a mid-sized company. I wouldn't call it a small company, relatively speaking, but I understand the Court's point, which is, you know, he's the CEO, he's speaking on it, he must know something about what's going on and, of course, he did. We're not saying he wasn't paying attention, he was asleep at the wheel or anything like that, but there are lots and lots of employees at this company doing lots of things. And they're developing a device.

The notion that the device is going to be perfect on day one and that the display is not going to blink and that the display is not going to go blank and there aren't going to be gibberish notes shown on the display on day one, is ridiculous. Of course those things happen. Of course they happen. It overheats. It goes to 99 instead of 97. Of course that happens.

It happens to, you know, Apple developing an iPhone. It happens all the time. But for people to come in, two years later and say, boy, I was at the company -- the phrase they

like to use is, even before the class period. Not even before the class period, only before the class period. This person wasn't there during the class period.

Sure, you saw those things. Of course you did. It's very easy to come back three years later, when something goes wrong and very unfortunate events take place, and say, I knew it all along. I knew that device was never going to work. I kept having problem, after problem with it. Of course you did. If these were easy to develop, everyone would do it. It's a lot of work that's very hard.

Was he optimistic? Yes. Did he display his optimism? Yes. Every time he spoke, were those not couched with anything could happen, knock on wood, we'll see. At one point, he says, the FDA might show up in three months, and if they do, maybe they'll find something, maybe they won't. I don't know. But if they do, we'll be wanting to fix it immediately.

And the plaintiffs say, that's false. Really? That's false? The FDA might show up in three months, and I don't know what's going to happen if they do and if they find something, I want to fix it, how is that false? Of course they're going to fix it. But that's the case we have here, lots of ex-employees saying I saw this, I saw that. Of course you did. That's not a fraud claim. It certainly doesn't reach the level of scienter.

The core operations theory is not a viable theory, and

it's certainly not a standalone theory. I just went through one through four and core operations was five, I believe -- actually, sorry, core operations was four. Five was Valtech. We cited to the Gentiva case on that point. The Valtech transaction cannot support an inference of scienter. It certainly cannot support an inference of scienter 13, 14 months before it was entered into. Again, most of what you heard about scienter was problems with the CE Mark trial, which didn't start until late 2015. That cannot support scienter for this class period.

THE COURT: All right. Thank you.

MR. ADLER: Thank you.

THE COURT: Why don't we adjourn for a few minutes, and then resume our proceedings. Thank you.

(Recess)

THE COURT: Be seated. I am prepared to rule, and in the interest of moving the case along, I'm going to rule orally today. You can, of course, obtain a transcript of today's proceeding.

In short, Defendants' motion is denied. I think Plaintiff has adequately pled its claims. I'm going to assume the parties' familiarity with the facts alleged in the Complaint, which are construed in the light most favorable to Plaintiff. See *Kleinman v. Elan Corp.*, 706 F.3d at 152.

The motion to dismiss standard is familiar. Plaintiff

must state enough facts to state a claim to relief that is plausible on its face. *Twombly*, 550 U.S. at 570. A claim has facial plausibility when it contains factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Iqbal*, 556 U.S. at 678.

Claims alleging securities fraud, moreover, are subject to additional pleading requirements. A claim under Section 10(b) of the Exchange Act sounds in fraud and must meet the requirements of Rule 9(b) of the Federal Rules of Civil Procedure and of the Private Securities Litigation Reform Act, the PSLRA, 15 U.S.C. 78u-4(b). Rule 9(b) requires a plaintiff to (1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent. *ATSI Communications, Inc. v. Shaar Fund, Ltd.*, 493 F.3d at 99.

The PSLRA, similarly, requires that a plaintiff specify each statement alleged to have been misleading and the reason or reasons why the statement is misleading. 15 U.S.C. 78u-4(b)(1). If an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed.

To state a claim under Sections 10(b) and 20(a) and

Rule 10b-5 promulgated thereunder, a plaintiff must allege that the defendant (1) made misstatements or omissions of material fact, (2) with scienter, (3) in connection with the purchase or sale of securities, (4) upon which the plaintiff relied, and (5) that the plaintiff's reliance was the proximate cause of its injury. *ATSI*, at 105.

Defendants have moved for dismissal of the Section 10(b) claim on the basis that Plaintiff has failed to plead sufficient facts with respect to the following three elements: that the identified statements were misleading; that Defendants acted with the requisite scienter; and that the purported misstatements caused Plaintiff's losses. If the Section 10(b) claim is dismissed, the 20(a) claim also fails.

A Section 10(b) plaintiff must demonstrate with specificity why and how a statement is false. See *Rombach v. Chang*, 355 F.3d at 174. Falsity is a failure to be truthful. It is not a misapprehension, misunderstanding, or misstatement of fact at the time a statement was made. In re: *Lululemon Securities Litigation*, 14 F. Supp. 3d at 571.

The veracity of a statement or omission is measured not by its literal truth, but by its ability to accurately inform rather than mislead prospective buyers. *Kleinman v. Elan Corp.*, 706 F.3d at 153. Statements that are literally true may become misleading based upon their context and manner of presentation. *Id.* Whether a statement is misleading

depends on the perspective of a reasonable investor. *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 135 S. Ct. at 1327.

Plaintiff alleges that Godshall made material misstatements and omissions with respect to three subjects: (1) HeartWare's efforts and success in remediating the deficiencies identified in the FDA Warning Letter; (2) MVAD's safety profile, particularly the effectiveness of its controller and the qPulse algorithm; and (3) MVAD's progress in the CE Mark trial.

While I am not going to rule on each of the almost 50 alleged misstatements, and some may not constitute material misstatements, I do find that there are well-pled allegations relating to each of these three topics.

Before turning to the alleged misstatements, I want to address Defendants' point about the degree to which Plaintiff relies on confidential sources. It appears that a split exists in this District as to whether the use of confidential witnesses to plead securities fraud cases remains viable following the Supreme Court's decision in *Tellabs*. Compare In re: *MRU*, 769 F. Supp. 2d at 516, with In re: *PXRE*, 600 F. Supp. 2d at 526, note 18.

At the very least, I believe it is appropriate to rely on such information where, as here, the Complaint provides a plausible basis for each confidential witness' knowledge and

the statements attributed to the witnesses are detailed, factual allegations rather than conclusory statements. See In re: PXRE, at note 18.

As to the first category of statements, Godshall's comments relating to the efforts and success in remediating the deficiencies described in the FDA warning letter, Plaintiff has alleged in detail why Godshall's statements were misleading. On an October 30, 2014, third-quarter earnings call, for instance, Godshall made the following comment: "Most importantly, we have made significant progress in our effort to address the FDA warning letter issues. The warning letter remediation project is an enormous undertaking by so many of our employees and impacts every aspect of our Company. We have upgraded many of our key procedures and are already seeing a positive impact from the new approach. We are working diligently through issues we find, as is evidenced by our battery replacement effort which began a few months ago."

These comments stand in contrast to Plaintiff's allegations that the company failed to undertake serious remediation efforts, which led to its lack of progress in resolving the issues identified by the FDA. The FDA warning letter provided a non-exclusive list of violations, which included: (1) failure to establish and maintain procedures for implementing corrective and preventive action; (2) failure to establish and maintain procedures for validating the device

design; (3) failure to validate computer software for its intended use, according to an established protocol when computers or automated data processing systems are used as part of production of the quality system, as required by 21 C.F.R. 820.70(i); and (4) failure to maintain a record of the investigation by the formally designated unit when an investigation is made, as the company did not document the likely or potential root cause, or document an attempt to obtain the complete nature and details of at least ten complaints which were submitted to FDA as MDR, medical device reporting, events.

However, according to Former Employee 5, a validation and verification tester from August 2012 to March 2015 who worked on MVAD, including its controller, after receiving the FDA warning letter, the manufacturing, testing, and validation processes at HeartWare didn't change, rather, we were just doing exactly what we were doing before receiving the letter.

Former Employee 5 also explained that, when MVAD failed validation tests, supervisors simply relaxed the relevant specification to allow the device to satisfy the standard. MVAD's original specifications, for instance, called for the controller's alarm to sound at a particular decibel, which it failed to do. Rather than devise a way to increase the decibel level, the minimum standard was altered to permit the device to pass muster.

Furthermore, MVAD's impeller was insufficiently tested as of the time of Employee 5's departure from HeartWare in March of 2015. Testing had been conducted on previous versions of the impeller, and the validation and verification team had access to the updated version of the impeller for only one week.

Former Employee 4, HeartWare's program manager for FDA 483 warning letter remediation for non-product software from March to August of 2014, further explained that adequate remediation of the problems identified in the warning letter would take years. Employee 4 continued, there were tremendous gaps between the R&D processes at HeartWare's headquarters versus what was practiced in the manufacturing facility, which was still the case when the employee left HeartWare in August of 2014.

Moreover, the company allegedly failed to document required specifications for raw materials and components manufactured by third-party contractors, and failed to test and audit those materials to ensure they met design requirements and were suitable for the device's intended use. This employee also explained that HeartWare had no process in place for auditing the software it used to test and validate its devices.

Employee 3, a corrective and preventative action manager at HeartWare from October 2014 to July 2015, buttressed these allegations, explaining that there was virtually no

quality assurance oversight at the company's Framingham headquarters and that HeartWare failed to create and maintain reliable deviation reporting, a reporting system for defects or flaws in the device, notwithstanding the FDA's instruction to remediate deficient corrective and preventative action procedures. When changes were made to a device, moreover, HeartWare had no system in place to monitor and evaluate those changes or to mandate retesting.

Plaintiff alleges that the failure to remediate the deficiencies noted in the warning letter continued through the end of the class period, i.e., the third quarter of 2015.

With respect to the second category of statements, Godshall's comments relating to the safety profile of MVAD and the effectiveness of its controller and the qPulse algorithm, plaintiff has similarly satisfied its burden.

On the same October 30, 2014, third-quarter earnings conference call, for example, Godshall stated that: Every data point we receive from bench testing, animal studies, and physician commentary is that the MVAD will be paradigm-changing.

Plaintiff has provided detailed allegations, however, as to the inadequacy of both MVAD's controller and the qPulse algorithm, which together rendered MVAD less safe than previous ventricular assist devices. These two features were of critical importance to MVAD's functionality because the

controller contained the device's alarm system, notifying patients and doctors when the pump created an imbalance of pressure on the left ventricle, while qPulse allowed MVAD to adjust its pumping speeds in an effort to reduce the frequency of adverse events.

Employee 1, HeartWare's director of program management from June 2008 to April 2014 and a member of HeartWare's leadership team, reporting first to the company's chief scientific officer, Jeff LaRose, and then to its senior vice president for research, development, and quality, Mark Strong, noted, for instance, the suction alarm, the algorithms, the qPulse displays that were blank or showed gibberish, those were problems that dogged the project throughout. Of the problems HeartWare had in the clinical trials, Employee 1 continued, I haven't heard of anything that wasn't on their radar screens early on.

With respect to the controller specifically, Employee 1 further explained that nothing really worked right. There were improper alarms, improper touch screen performance, gibberish on display screens, just so many alerts and problems and it wasn't working at all reliably. There was also a total lack of reliability and robustness in the design of the software to make the controller function properly. Moreover, there were literally more than 100 hot and critical issues tracked on a daily basis trying to fix them when I left, and

that was in April of 2014.

Many of these issues stemmed, in the employee's opinion, from management's continued use of Band-Aid solutions for basic, inherent problems that no one wanted to listen to early on. Instead of doing it right, they got so far down the pathway that either you take an eight-month hit to resolve the issues, or you say this is the best you can do and you make it acceptable.

Employee 5, and other HeartWare personnel, observed and reported that the suction alarm on the controller was defective, corroborating Employee 1's account. MVAD's alarm, according to Employee 5, would not trigger except under the most extreme conditions.

There were also purportedly well-known flaws with respect to the qPulse algorithm. Employee 2, a senior software engineer throughout the class period, for example, reported that significant risks were found with the MVAD's pump pressure algorithm, which was designed to reset the device if internal pressure caused the pump's impeller to move too far out of place.

Aspects of MVAD's unique design, Employee 2 explained, guaranteed that the impeller would be forced out of place and would strike the ends of the impeller housing, grinding blood cells like a mortar and pestle, which would likely cause clots and promote pump thrombosis.

The pump pressure algorithm was tasked with detecting that we hit the end of the pump, we had a strike, and reducing the pump speed because HeartWare's testing had shown that below a certain speed, you could not get it to strike; so you want to reduce the speed and then slowly return it to the former speed.

Employee 2 explained, however, that because the algorithm was hastily designed, it failed to properly slow the pump. A consultant was hired to examine this issue, but when the consultant discovered that the pump pressure algorithm failed to prevent the impeller from grinding against the pump housing, HeartWare's chief scientific officer, who reported directly to Godshall, told those working on the investigation to cease and desist.

Together, these flaws, as alleged by plaintiff, painted a clear picture of a flawed product, not one that, based on all data points, would be "paradigm changing" as Godshall claimed.

I also find that Plaintiff has pled sufficient facts to survive defendant's motion to dismiss with respect to the final category of claims relating to the CE Mark trial.

On October 29, 2015, HeartWare issued a press release announcing its third-quarter financial and operating results. The release noted that: We are also reviewing reported adverse events, which are typical of those seen in other clinical trials for ventricular assist devices, and we are confident

that we will resolve the issue in order to resume the MVAD CE Mark clinical trial.

Plaintiff alleges that HeartWare knew that it was unlikely to resume the CE Mark trial because the results to that point were far from typical. In particular, the 27 percent incidence rate of pump thrombosis was seven to 13 times the rate reported in early clinical trials of competing devices that contributed to VAD market growth, and at least three times the rate reported in an NEJM study that had contributed to the stagnation of the VAD market.

Moreover, the thromboses observed in the CE Mark trial occurred more quickly after device implantation, approximately six times faster than reported in competing devices and more than twice as quickly as such incidents had occurred in HVAD patients.

Defendants argue that Godshall's comments were not misleading because they concerned the events being analyzed rather than their frequency and that pump thrombosis is, in fact, a common adverse event in VAD trials. The disclosure that adverse events had occurred and the description of them as being typical, however, renders the statement objectively misleading, given that the events had allegedly occurred with substantial frequency and so soon after implantation. These purported facts also belie HeartWare's claim that it was confident that the CE Mark trial would resume.

Contrary to Defendants' arguments, moreover, none of the purported misleading statements upon which I base my ruling are forward looking, inactionable statements of honestly held opinions or so vague as to constitute statements of corporate optimism.

Pursuant to the PSLRA, a well-pled securities fraud claim must state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind. 15 U.S.C. 78u-4(b)(2). The issue is whether all of the facts alleged, taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard. *Tellabs, Inc. v. Makor Issues & Rights,* 551 U.S. at 322 to 23.

A strong inference of scienter, moreover, must be more than merely plausible or reasonable. It must be cogent and at least as compelling as any opposing inference of non-fraudulent intent. *Id.* at 314.

In this Circuit, a strong inference of scienter can be established by alleging facts to show either (1) that defendants had the motive and opportunity to commit fraud, or (2) strong circumstantial evidence of conscious misbehavior or recklessness. *ECA v. JP Morgan Chase Co.*, 553 F.3d at 198.

Because I find that Plaintiff has alleged circumstantial evidence of, at the very least, recklessness, I need not address whether Plaintiff has sufficiently pled motive

and opportunity. A plaintiff adequately pleads recklessness where he alleges that the defendant knew facts or had access to information contradicting its public statements; or (2) failed to review or check information that it had a duty to monitor. See *Novak*, 216 F.3d at 308.

Plaintiff has adequately alleged scienter when all the allegations are considered, not individually but in tandem, pursuant to the Tellabs standard. The complaint contains facts that would allow a reasonable person to infer that scienter is at least as compelling as any opposing inference.

The following factors, particularly when considered together, properly make out scienter: First, in response to concern over rumors of adverse events in the CE Mark trial, Godshall told investors those adverse events were "typical of those seen in other clinical trials for ventricular assist devices" even though Defendants allegedly possessed data showing that MVAD was causing adverse events at a rate substantially surpassing the norm and far more quickly than was typical;

Second, MVAD's deficiencies, including defects in the controller alarm and qPulse algorithm, were allegedly repeatedly discussed at meetings attended by Godshall, including weekly MVAD meetings and monthly project oversight board meetings, reflected in meetings of minutes Godshall received, and widely reported and discussed within HeartWare,

even before the class period began;

Third, Godshall repeatedly stated that he was personally focused on the details of MVAD's development and commercialization, which means he either failed to perform the monitoring he claimed to have performed or recklessly misrepresented the circumstances to plaintiffs;

Fourth, many of Godshall's public statements concerned issues specifically raised by the FDA in the warning letter regarding a key product of the corporation, see e.g., In re: *Delcath Systems, Inc. Securities Litigation*, 36 F. Supp. 3d at 335, which is a small company or even a medium-sized company, as defendant contends, with only one manufacturing facility, and thus, management's attention is less likely to be divided.

Finally, the magnitude of the alleged fraud here further weighs in favor of a strong inference of scienter, see In re: *Salix Pharm.*, 2016 WL 1629341, at 16.

These facts, taken together, raise a strong inference that Godshall, at a bare minimum, had access to information that contradicted his public statements regarding the company's remediation efforts, the safety profile of MVAD, and HeartWare's progress in the CE Mark Trial.

Finally, I must address whether plaintiff has adequately pled loss causation. Loss causation is the causal link between the alleged misconduct and the economic harm ultimately suffered by a plaintiff. See *Lentell v. Merrill*

Lynch & Co., 396 F.3d at 172. This question is not meant to impose a great burden on plaintiffs. *IBEW Local 90 v. Deutsche Bank AG*, 2013 WL 1223844 at 12.

Moreover, loss causation is subject to the less-onerous notice pleading requirements of Federal Rules of Civil Procedure 8(a)(2) in lieu of the rule 9(b) standard. See *id.* To establish loss causation, therefore, a plaintiff must only show that the loss was a foreseeable result of the defendant's conduct, i.e. the fraud, and that the loss was caused by the materialization of the risk concealed by the defendant's alleged fraud. See in re: *Vivendi, S.A. Securities Litigation*, 838 F.3d at 261.

Put more simply, proof of loss causation requires demonstrating that the subject of the fraudulent statement or omission was the cause of the actual loss suffered. *Id.* It is enough, for instance, that the loss caused by the alleged fraud results from the relevant truth leaking out. *Id.* Indeed, when the truth comes out by way of a corrective disclosure describing the precise fraud inherent in the alleged misstatements, or through events constructively disclosing the fraud, does not alter the basic loss-causation calculus. *Id.* at 262.

Here, Plaintiff has adequately pled loss causation. Plaintiff alleges three separate events due to which it suffered losses: First, when HeartWare’s stock fell 21 percent

the day following the announcement of the Valtech Transaction; second, when HeartWare's stock price fell approximately 30 percent during the trading day immediately following the October 12, 2015, disclosure that defendants had observed adverse events in the CE Mark Trial and would further delay resumption of the trial in order to investigate; and, finally, on January 11, 2016, when the value of HeartWare's stock declined more than 35 percent following the announcement that nearly half of the patients in the CE Mark Trial had experienced pump thrombosis, that qPulse and the suction alarm appeared to elevate the risk of thrombosis, and that the trial would be paused indefinitely.

In each of these events, the market's reaction to the announcement demonstrates that the "relevant truth" had, at least in part, leaked out. *Vivendi*, at 261. Each event revealed additional information about MVAD, allegedly in contravention of public statements made by defendants, and precipitated an immediate and marked decline in the value of shares of HeartWare's stock.

While the connection between the alleged misstatements and the Valtech transaction is perhaps more attenuated, particularly in light of the admitted significance of MVAD to HeartWare's future profitability and the timing of the announcement of the Valtech transaction, this event suffices as a basis for pleading loss causation. Plaintiff has, thus,

sufficiently pled loss causation.

So for all of those reasons, plaintiff has sufficiently pled each and every element of a section 10(b) violation, and defendants' motion to dismiss is denied. Because defendants' motion to dismiss with respect to the control person claim under section 20(a) rests entirely upon their argument that plaintiff has failed to plead the predicate 10(b) violation, the motion to dismiss is also denied as to the section 20(a) claim against Godshall.

All right. Thank you all for your patience. I think that this is more efficient to get the ruling faster. We can move forward with the case. How long do defendants need to file an answer?

MR. BONGIORNO: Like 60 days, your Honor. I have discussed not the number of days but an extension with plaintiff's counsel.

THE COURT: That's fine.

MR. BONGIORNO: And I think they're amenable.

THE COURT: All right. So we'll just make it May 16th. All right?

MR. BONGIORNO: Thank you.

THE COURT: Is there anything else we need to discuss today? All right.

MR. RIZIO-HAMILTON: No, your Honor.

THE COURT: Thank you. I said it at the start, but I

thought the advocacy on both sides was really outstanding, and so I want to thank you for that. Enjoy the weekend.

MR. BONGIORNO: Thank you, your Honor.

MR. RIZIO-HAMILTON: Thank you, your Honor.

(Adjourned)